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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,056	01/11/2001	Diane Pennica	GENENT.2827A2	1938

7590 11/26/2004

Katherine Kowalchyk
P.O. Box 2903
Minneapolis, MN 55402-0903

EXAMINER	
BORIN, MICHAEL L	
ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 11/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/759,056	PENNICA ET AL.	
	Examiner	Art Unit	
	Michael Borin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09/20/2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-4,8-11,15,16,18-21 and 96-106* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *2-4,8,15,16 and 18-21* is/are allowed.

6)☐ Claim(s) *9-11,96 and 99-106* is/are rejected.

7)☒ Claim(s) *97 and 98* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Response filed 09/20/2004 is acknowledged. Claims 2-4,8-11,15,16,18-21, 96-106 are pending.

2 Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Priority

3. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional applications upon which priority is claimed seem to fail to provide adequate support under 35 U.S.C. 112 for the SEQ ID NOs of the instant invention. No CRF was filed with the provisional applications to which priority is claimed. It is possible that the provisional application recites a sequence which is the same as instant SEQ ID NOs, but in the absence of a CRF for the application, the examiner is not able to determine whether any sequence recited in the provisional application is identical to instant SEQ ID Nos. Applicant is requested to point to the specific SEQ ID number(s) in any or each of the provisional applications that correspond to instant SEQ ID NOs, and to the specific

page and line, or to the specific page and Table designation where the corresponding SEQ ID NOs. are taught. In the absence of any indication of such correspondence and/or an alignment showing identity between SEQ ID NOs, priority is not granted to the provisional application, and the instant application is granted priority only to its filing date.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 96,99 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn polynucleotides encoding PRO10282 polypeptide which has nine potential transmembrane domains identified on Fig. 9. Neither Fig. 9, nor description in the specification (p. 10, last paragraph which addresses boundaries of the domains in relative "from about position *"x"* to about position "y" terms), clearly identify the sequence of each of the domains. Consequently, it is not clear what products are encompassed by the scope of the claims.

Claim Rejections - 35 USC § 112, first paragraph (written description)

5. Claims 9-11 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 9 introduces new matter by reciting that isolated nucleic acids encoding a PRO10282 peptide encode peptide which is at least 100 amino acids in length. Examiner agrees with applicant that specification, p. 33 addresses nucleic acids that encode an active PRO 10282 peptides. However p. 26, lines 23-24, defines that in terms of fragments that are "active PRO 10282 peptides", the fragments are "specifically derived fragments of SEQ ID No. 2" (emphasis added). There is no definition of "specifically derived fragments" for fragments having 100 or more residues as is now claimed in claim 9.

6. Claims 96,99,100-106 are rejected under 35 U.S.C. 112, first paragraph (written description) as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The rejection is maintained for the reasons of record and further in view of the following.

Claim 106 is drawn to polynucleotides comprising DNA having at least 99% degree of identity with polynucleotide positions 49-2049 of SEQ ID No. 1. As described in the specification, the polynucleotide SEQ ID No. 1 (polynucleotide positions 49-2049 of which encode protein SEQ ID No. 2) is overexpressed in cancer tissues and thus can be used for cancer diagnostics. Polynucleotide SEQ ID No. 1 itself meets the written description and enablement provisions of 35 USC 112, first paragraph. However, the claims as drawn to polynucleotides DNA having at least 99% degree of identity with polynucleotide positions 49-2049 of SEQ ID No. 1, do not have sufficient description in the specification as description of species is insufficient to support a highly variable genus. Applicant is advised that absent factual evidence, a percentage sequence similarity of less then 100% over the entire length is not deemed to reasonably support to one skilled in the art whether the biochemical activity of newly discovered sequence would be the same as that of similar known biomolecule. The effects of changes in the structure are largely unpredictable as to which ones have a significant effect versus not. No sequence information indicating what is the necessary common attribute for the polynucleotides encompassed by the claimed genus to be useful in the detection of cancer are present in the specification. Therefore, sequence similarity result in an unpredictable and therefore unreliable correspondence between the newly discovered sequence and a similar biomolecule of known function or expression. With the exception of SEQ ID NO:1, the skilled artisan cannot envision the detailed

chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. Accordingly, the specification does not provide a written description of the polynucleotide as claimed, and, consequently, of their complement. Note, that even though specification indicates that SEQ ID Nos. 2,5 contain open reading frame encoding protein SEQ ID NO:2 or 5, the claims are not drawn to polynucleotides encoding a particular protein. The specification provides insufficient written description to support the genus encompassed by the claim.

Claims 96,99 are drawn to polynucleotides having at least 99% degree of identity with polynucleotide encoding a[ny] PRO10282 and having nine potential transmembrane domains identified on Fig. 9. There is no description of any polypeptides other than protein SEQ ID No. 2 that have said potential domains and there is no description of these domains themselves specific enough to identify the structure of the molecule claimed. Note that neither Fig. 9, nor description in the specification (p. 10, last paragraph) clearly identify the sequence of each of the domains. Accordingly, the specification does not provide a written description of the polynucleotide as claimed, and, consequently, of their complement.

Claims 102, 103 are drawn to polynucleotides having at least 99% degree of identity with polynucleotide encoding a[ny] PRO10282 polypeptide, wherein the

latter binds an[y] antibody raised against protein SEQ ID No. 2. There is no written description of epitopes of SEQ ID No. 2 recognizable by an antibody against protein SEQ ID No. 2; thus there is no description of genus of PRO10282 polypeptides that would bind an[y] antibody raised against protein SEQ ID No. 2. Note that PRO10282 peptides are defined in the specification merely as polypeptides having sequence similarity to murine Stra6 (see specification, p.1).

Examiner maintains that the specification provides insufficient written description to support the genus encompassed by the claims.

Claim Rejections - 35 USC § 112, first paragraph (enablement)

8. Claims 9,10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid SEQ ID NO:1, does not reasonably provide enablement for polynucleotides hybridizable to SEQ ID No. 1 and encoding a fragment of SEQ ID No. 2.

As described in the specification, the polynucleotide SEQ ID No. 1 (which encodes protein SEQ ID No. 2) is overexpressed in cancer tissues and thus can be used for cancer diagnostics. No information about overexpression of any other polynucleotides, e.g., polynucleotides having certain degree of hybridization to the polynucleotide SEQ ID No. 1 is present in the specification. Similarly, whereas specification teaches that polypeptide SEQ ID No. 2 (encoded by the polynucleotide SEQ ID No. 1) is overexpressed in cancer tissues, there is no teaching that overexpression of polypeptides comprising fragments of SEQ ID 2 can be indicative of cancer development. Consequently, with the insufficient guidance and working

examples, one skilled in the art could not use the invention with as claimed without an undue amount of experimentation.

9. Claims 96,99-101 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid encoding polypeptide SEQ ID NO:2 (e.g., polynucleotide SEQ ID No. 1), does not reasonably provide enablement for polynucleotides having at least 99% degree of identity with polynucleotide encoding a[ny] PRO10282 and having nine potential transmembrane domains identified on Fig. 9. As there is no description of these nine domains themselves specific enough to identify the structure of the molecule claimed, nor there is description of any polypeptides other than protein SEQ ID No. 2 that have said potential domains, the structural limitation claimed is not clear. Consequently, one skilled in art would not know how to make invention as claimed. and. Note that neither Fig. 9, nor description in the specification (p. 10, last paragraph) clearly identify the sequence of each of the domains. Accordingly, the specification does not provide a written description of the polynucleotide as claimed, and, consequently, of their complement.

Claim Rejections - 35 USC § 102

10. Claims 9-11 are rejected under 35 U.S.C. 102(a) as being anticipated by the sequence of Database GenEmbl, accession number AAV84436. The referenced sequence shows 92% local similarity to a fragment of nucleic acid SEQ ID No. 1 (i.e, nucleic acid encoding residues 1-667 of protein SEQ ID No. 2; see sequence alignment attached to Office action mailed 10/31/2002). As such, the referenced nucleic acid has continuous stretches matching the claimed polynucleotide, and it will hybridize to nucleic acid encoding residues 1-667 of protein SEQ ID No. 2, in particular under high stringency conditions (absent evidence to the contrary).

Response to arguments

Upon reconsideration of the original rejection (see Office action mailed 10/31/2002) and applicants arguments, the rejection is reiterated. Applicant seem to keep arguing (see amendment filed 11/21/2003, p. 13) argues that because the overlapping part of the referenced sequence aligns with residues 1768-2049, the referenced sequence would not encode a PRO 10282 peptide having more than 100 residues. However, as previously indicated by Examiner, the alignment covers a much longer stretch of SEQ ID No. 1: nucleotides 1768-2663, not 1768-2049 as erroneously indicated by applicant; therefore the referenced sequence would encode a PRO10282 peptide having more than 100 residues. Further, even if the overlap of aligned sequences had been shorter than 300 nucleotides, the referenced sequence is still is longer than 850 nucleotides and is thus capable of encoding a peptide having more than 100 residues. The latter will be still considered a PRO10282 peptide as it has some sequence similarity to peptide SAQ ID No. 2, and PRO10282 peptides are defined in the specification as

polypeptides having sequence similarity to murine Stra6 (see specification, p.1). Further, specification defines PRO10282 peptide as having as few as at least about 10 amino acids (p. 27, line 21).

Double Patenting

11. It is noted that the applicant filed an extensive family of applications that share the same subject matter, protein PRO10282 and nucleic acids encoding thereof, with the claims of the instant application. See, for example, applications 10/119480, 10/216160. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Since the actual claimed subject matter depends on the results of applying restriction practice, applying double-patenting rejection is deferred until completion of identifying of the allowable subject matter in the instant application.

Conclusion

12. Claims 2-4,8,15,16,18-21 are allowable.

13. Claims 97,98 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form (although then they will duplicate claims 2,3, respectively).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Borin, Ph.D.
Primary Examiner
Art Unit 1631

mlb